

REMARKS

Claims 1-33 are pending before the Office. Claims 1, 4, 6, 12, 15, 19 and 22 have been amended. Claims 31-33 have been canceled. Support for the claim amendments may be found throughout the specification, namely at p. 18 and Fig. 3.

I. Rejection under 35 USC §112:

Claims 31-33 are rejected under 35 USC §112, 1st paragraph, as allegedly lacking enablement for the prevention of cartilage degradation. Applicant respectfully submits this rejection has now been rendered moot as the subject claims 31-33 have been canceled by way of amendment. Accordingly, Applicant requests Examiner withdraw the noted rejection, as applied to claims 31-33.

Claims 6 and 31-33 are rejected under 35 USC §112, 2nd paragraph as being allegedly indefinite. Applicant has cured such defect by way of amendment. Specifically, with respect to claim 6, the claim now recites similar statements of scope with respect to the claimed limitation. Claim 6 has been amended to remove the "device" recitation. The rejection is now moot with respect to claims 31-33, as the subject claims have been canceled by way of amendment. Accordingly, Applicant requests Examiner withdraw the noted rejection, as applied to claims 6 and 31-33.

II. Rejection under 35 USC §102:

Claims 1-2, 18-19, 22-24 and 27-28 are rejected under 35 USC §102(b) as being allegedly anticipated by US 5,587,363 (hereinafter, Henderson). Specifically, Henderson allegedly anticipates each and every claim limitation in the present

application. Based on the arguments below, as well as the present amendments to the claims, Applicant respectfully requests Examiner withdraw the §102 rejection as applied to claims 1-2, 18-19, 22-24 and 27-28.

As Examiner is well aware, a single prior art reference must disclose each and every limitation of the subject claims, either expressly or inherently, to qualify as a prior anticipatory reference (*Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998); *American Hospital Supply v. Travenol Labs*, 745 F.2d 1 (Fed. Cir. 1984)). Additionally, there must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art (*Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)).

Henderson teaches therapeutic compositions for the repair of connective tissue in humans and animals, wherein the compositions are composed of two distinct materials: an aminosugar and a glycosaminoglycan (hereinafter, GAG). The principle behind Henderson's disclosure is that only one of the materials, either only an aminosugar or only a GAG, is insufficient as a treatment for repairing tissue damage (*Henderson*, col. 3, lines 19-31). Most notably is the teaching described in Henderson that a composition is unsatisfactory as a therapeutic in this field without some ability to increase GAG production (*Id.*). Furthermore, Henderson continues to state that none of the present art compositions have both the aminosugar starting material used in conjunction with a GAG, essentially stating that the composition will not serve its intended purpose unless BOTH materials are included to assist in

the conversion of the material to protoglycans for facilitating tissue repair (*Henderson*, col. 2, line 37 to col. 3, line 31).

In contrast to *Henderson*, claim 1 of the instant invention specifically recites a method of treating a pathology related to synovitis, subchondral bone edema or cartilage degradation wherein the treatment involves administration of an aminosugar by intra-articular injection. *Henderson* is silent on several elements of all subject claims, most notably the intra-articular injection recitation added by the present amendments to the claims. Furthermore, *Henderson* fails to anticipate each and every element of the subject claims, including "diagnosing a pathological marker" (claim 18) and "injectable formulations" (claim 1, 27, etc.). Accordingly, Applicant respectfully requests Examiner withdraw the §102 rejection as applied to claims 1-2, 18-19, 22-24 and 27-28, as *Henderson* fails to qualify as a proper anticipatory reference.

Claims 1-2 are rejected under 35 USC 102(b) as being allegedly anticipated by US 4,870,061 (hereinafter, *Speck*).

Speck teaches a method of treating degenerative disorders of the joints and connective tissues comprising administering buccally an amount of N-acetylglucosamine (hereinafter, GlcNAc) sufficient to treat the degenerative diseases. *Speck* only mentions the intra-articular administration of glucosamine sulfate and only to the extent that it cannot be administered alone but, rather, must be administered with an additive (such as lidocaine) due to the pain caused by injection into the joint (*Speck*, col. 2, lines 16-34). Additionally, *Speck* is silent on the conditions described in the claim recitations of claim 1,

namely synovitis, subchondral bone edema, and cartilage degradation. Accordingly, Applicant respectfully requests Examiner withdraw the §102 rejection as applied to claims 1-2, as Speck fails to qualify as a proper anticipatory reference.

III. Rejection under 35 USC §103:

Claims 1-30 are rejected under 35 USC §103 as being allegedly unpatentable over Henderson in view of Speck, US 5,169,636 (hereinafter, Nanba), US 5,843,919 (hereinafter, Burger), US 5,863,551 (hereinafter, Woerly), US 6,506,784 (hereinafter, "Evans) and WO 00/68194 (hereinafter, Wong).

MPEP §2143.02 states, "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." (*In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Henderson and Speck have been discussed *supra*. Both references are limited to oral/buccal administration and are silent as to the limitations of the instant invention. The claims as presently amended reflect recitations not considered in either Henderson or Speck. Specifically, the intra-articular administration of the aminosugar is not considered in Henderson or Speck. In fact, Speck never considered the therapeutic advantages or chondroprotective effects of the intra-articular element. Furthermore, one of skill in the art would not be motivated to combine Henderson and Speck, as each suggests contrasting elements. Henderson requires two specific materials in the composition, namely an aminosugar and a GAG. Speck, on

the other hand, only involves GlcNAc to be buccally administered. Courts have held an invention nonobvious where one prior art reference taught away from a combination with a second prior art reference (*In re Rudko*, Civ. App. No. 98-1505 (Fed. Cir. 1999)). These two references combine to form an allegedly inoperable invention, as Speck discloses a form which is incongruent with the teachings of Henderson due to a lack of an additional component to stimulate proteoglycan formation (Henderson, col. 6, lines 28-35).

The additional references cited fail to remedy the defects in Henderson and Speck. Nanba is drawn to formulations comprising aminosugars encapsulated within liposomes. Burger is drawn to formulations comprising gels. Woerly teaches formulations within matrices. Evans teaches combining anti-inflammatory agents with glucosamine in various forms. Wong teaches hexoaminidases and their catabolism of GAGs and the development of inhibitors of same.

The claims of the instant invention are not obvious over any combination of the above references. Nanba is drawn to a complete reformulation of a part of the composition within Henderson. As stated *supra*, Henderson teaches, as a necessary requirement, a composition composed of two distinct materials. One of skill in the art would immediately realize the value, based on the teachings in Henderson, of having both materials. None of the above references involve both materials. Accordingly, it would not be reasonable that one of skill in the art would be motivated to combine references that teach only one of the starting materials in Henderson. Accordingly, Applicant respectfully requests Examiner withdraw the §103 rejection as

applied to claims 1-30, as an obviousness rejection cannot be maintained in light of the teaching within the art of record when compared to the claims of the instant invention.

IV. Conclusion:

Applicant respectfully submits the claims in their present form are now in condition for allowance. Accordingly, Examiner is kindly requested to withdraw the rejections described above and allow the present claims. Examiner is encouraged to contact the undersigned to discuss any additional matters in the present application.

Respectfully submitted,

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